comprises SEQ ID NO: 1, 2 or 18.

35. The method of claim 34 wherein the BCSG polynucleotide comprises SEQ ID NO:1.

36. The method of claim 34 wherein the BCSG polynucleotide comprises SEQ ID NO:2.

37. The method of claim 34 wherein the BCSG polynucleotide comprises SEQ ID NO:18.

REMARKS

Claims 1-17 are pending in the instant application. Claims 1, 2 and 8-17 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this amendment. Claims 3-7 have been rejected. Claims 3-7 have been amended. New claims 18 through 37 have been added. No new matter has been added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement set forth in the Office Action mailed June 15, 2001. Accordingly, in an earnest effort to advance the prosecution of this case,

Applicants have canceled claims 1, 2 and 8-17, without prejudice. However, in light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Objection to Specification

The objections to the specification set forth in the Office Action mailed June 15, 2001 have been maintained because a marked up version of the amendments to the specification and abstract was not submitted. Accordingly, Applicants are resubmitting herewith the amendments to the specification as well as a marked up version of these amendments. Specifically, Applicants are providing a replacement Abstract herewith which has been amended to enable the reader to ascertain quickly the character of the subject matter covered by this disclosure. Applicants have also amended the specification to capitalize TAQMAN and have provided the generic terminology for this trademark where the term is first presented in the specification. No new matter has been added by these amendments.

Withdrawal of the objections to the specification is respectfully requested in light of these amendments and Applicants submission of a marked up version of these amendments.

III. Rejection of Claims 3-7 under 35 U.S.C. § 112, first paragraph

The rejection of claims 3-7 under 35 35 U.S.C. § 112, first paragraph, has been maintained. However, the Examiner has acknowledged that the claims may be allowable if amended to recite "determining levels of BCSG mRNA or polynucleotide" or some other language supported by the specification, which indicates polynucleotide levels were determined.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to state that BCSG polynucleotide levels are determined. Support for this amendment can be found throughout the specification and in particular at page 3, line 2-26, page 4, line 4-11, page 7, line 3-34 and in claim 1 as originally filed. In addition, Applicants have added new dependent claims 18-37 drawn to specific BCSG polynucleotide described in detail in the specification at pages 27-37. No new matter has been added by this amendment.

Withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested in light of these amendments to the claims.

IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**."

Respectfully submitted,

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Date: **August 7, 2002**

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

At page 21, please replace the paragraph at lines 22-30 with the following paragraph:

--Real-Time quantitative PCR with fluorescent ~~Taqman~~ TAQMAN probes (internal fluorescent oligonucleotide probes labeled with a 5′ reporter dye and a downstream, 3′ quencher dye) is a quantitation detection system utilizing the 5′- 3′ nuclease activity of Taq DNA polymerase. ~~The method uses an internal fluorescent oligonucleotide probe (Taqman) labeled with a 5′ reporter dye and a downstream, 3′ quencher dye.~~ During PCR, the 5′-3′ nuclease activity of Taq DNA polymerase releases the reporter, whose fluorescence can then be detected by the laser detector of the Model 7700 Sequence Detection System (PE Applied Biosystems, Foster City, CA, USA).

At page 22, please replace the paragraph at lines 9 through 19 with the following paragraph:

--The tissue distribution, and the level of the target gene were determined for every sample in normal and cancer tissue. Total RNA was extracted from normal tissues, cancer tissues, and from cancers and the corresponding matched adjacent tissues.

Subsequently, first strand cDNA was prepared with reverse transcriptase and the polymerase chain reaction was done using primers and ~~Taqman~~ TAQMAN probe specific to each target gene. The results were analyzed using the ABI PRISM 7700 Sequence Detector. The absolute numbers are relative levels of expression of the target gene in a particular tissue compared to the calibrator tissue.--

Please delete the Abstract at page 28 and replace it with the following:

~~The present invention provides new markers and methods for detecting, diagnosing, monitoring, staging, prognosticating, imaging and treating breast cancer.~~

Diagnostic markers for breast cancer referred to herein breast cancer specific genes or BCSGs are provided. Also provided are methods for using BCSGs to detect, diagnose, monitor, stage, prognosticate, image and treat breast cancer. Antibodies which specifically bind BCSGs and methods of using these antibodies to image and treat breast cancer are also provided.

In the claims:

Please cancel claims 1, 2 and 8-17, without prejudice.

Please amend the claims as follows:

3. (amended) A method for diagnosing the presence of breast

cancer in a patient comprising:

(a) determining levels of Breast Cancer Specific Gene (BCSG) polynucleotide in cells, tissues or bodily fluids in a patient; and

(b) comparing the determined levels of BCSG polynucleotide with levels of BCSG polynucleotide in cells, tissues or bodily fluids from a normal human control, wherein an increase in determined levels of BCSG polynucleotide in said patient versus normal human control is associated with the presence of breast cancer.

4. (amended) A method of diagnosing metastases of breast cancer in a patient comprising:

(a) identifying a patient having breast cancer that is not known to have metastasized;

(b) determining Breast Cancer Specific Gene (BCSG) polynucleotide levels in cells, tissues, or bodily fluid from said patient; and

(c) comparing the determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissue, or bodily fluid of a normal human control, wherein an increase in determined BCSG polynucleotide levels in the patient versus the normal human control is associated with breast cancer which has metastasized.

5. (amended) A method of staging breast cancer in a patient

having breast cancer comprising:

(a) identifying a patient having breast cancer;

(b) determining Breast Cancer Specific Gene (BCSG) polynucleotide levels in a sample of cells, tissue, or bodily fluid from said patient; and

(c) comparing determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or bodily fluid of a normal human control, wherein an increase in determined BCSG polynucleotide levels in said patient versus the normal human control is associated with breast cancer which is progressing and a decrease in the determined BCSG polynucleotide levels is associated with breast cancer which is regressing or in remission.

6. (amended) A method of monitoring breast cancer in a patient for the onset of metastasis comprising:

(a) identifying a patient having breast cancer that is not known to have metastasized;

(b) periodically determining levels of Breast Cancer Specific Gene (BCSG) polynucleotide in samples of cells, tissues, or bodily fluid from said patient; and

(c) comparing the periodically determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or bodily fluid of a normal human control, wherein an

increase in any one of the periodically determined BCSG polynucleotide levels in the patient versus the normal human control is associated with breast cancer which has metastasized.

7. (amended) A method of monitoring a change in stage of breast cancer in a patient comprising:

(a) identifying a patient having breast cancer;

(b) periodically determining levels of Breast Cancer Specific Genes (BCSG) polynucleotide in cells, tissues, or bodily fluid from said patient; and

(c) comparing the periodically determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or bodily fluid of a normal human control, wherein an increase in any one of the periodically determined BCSG polynucleotide levels in the patient versus the normal human control is associated with breast cancer which is progressing in stage and a decrease is associated with breast cancer which is regressing in stage or in remission.